K02 1583

AUG 1 2 2002

510 (k) Summary of Safety and Effectiveness for PatXfer

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
Phone: +49-89-99 15 68-0
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Contact Person: Mr. Stefan Vilsmeier

Summary Date: May 6. 2002

Device Name:

Trade name: PatXfer

Common/Classification Name: PatXfer / Picture Archiving and Communication System

Predicate Device: VectorVision

Device Classification Name: Picture Archiving and Communication System
Regulatory Class: Class II

Intended Use:

PatXfer provides capabilities for the acceptance, transfer, display, storage and digital processing of medical images including functions for performing operations related to image manipulation, enhancement, compression and quantification.

Device Description:

PatXfer intends to interface between medical devices and provide the patient data for treatment plan.
The application provides capabilities for the transfer, display, storage and digital processing of medical images. PatXfer supports scanner specific and standard data formats from digital storage media, such as network archive, optical disk, tape, CD-ROM or hardcopy. To facilitate the imaging and communication with other medical systems the DICOM format and protocol is supported.

To keep the application as user-friendly as possible only the necessary information for the intended procedures are displayed. The patient, image series and images will be displayed and can be selected and processed. PatXfer creates a history log-file including all the software actions to import the data and can be controlled with the mouse or by touch screen monitor.

Typical users of this system are trained professionals, including but not limited to physicians, nurses and technicians.

Substantial equivalence:
PatXfer has been verified and validated according to BrainLAB's procedures for product design and development and found to be substantially equivalent with BrainLAB medical devices such as VectorVision^2 (K 983831). The validation proves the safety and effectiveness of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Mr. Stefan Vilsmeier
President
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
GERMANY

Re: K021583
Trade/Device Name: PatXfer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 6, 2002
Received: May 14, 2002

Dear Mr. Vilsmeier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021583

Device Name: PatXfer

Indications For Use:

PatXfer provides capabilities for the acceptance, transfer, display, storage and digital processing of medical images including functions for performing operations related to image manipulation, enhancement, compression and quantification.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

/s/ David G. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021583